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EXAMINER

LANEAU, RONALD

ART UNIT PAPER NUMBER

3627

DATE MAILED: 08/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/942,803

Applicant(s)

MCQUADE ET AL.

Examiner

Ronald Laneau

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-8 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Response to Amendment

1. The amendment filed on 05/05/2004 has been entered. Claims 4 and 9 are canceled, claim 10 is added and claims 1-3, 5-8 and 10 are now pending.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-3, 5-8 and 10 are rejected under 35 U.S.C. 103(a) as being obvious over the product SampleTrakTM incorporating PhasTrakTM as primarily taught in BusinessWire, IMS Health Strategic Technologies Launches SampleTrak, the First Web-Based Solution for Managing prescription Drug Sampling, April 19, 2000, pg. 1.

As per claim 1, BusinessWire teaches a method of tracking the distribution of controlled articles from a central inventory by means of electronic communication and data collection, comprising: receiving in a system server, a distribution request from a remote distributing representative for distribution of a packet of articles to a distributee (Field representatives are able to order samples and receive shipment acknowledgement via the Web), the request comprising a representative identifier, a distributee identifier (announced the launch of SampleTrakTM, a unique, integrated product that provides pharmaceutical companies with a complete solution for meeting prescription Drug Marketing Act Final Rules in the U.S. . . . SampleTrak enables pharmaceutical administrators to electronically validate a physicians

eligibility to receive samples . . . verified signature of a physician receiving a sample) , and a statement describing the contents of the packet of articles being distributed from a local inventory associated with the distributing representative (SampleTrak can be seamlessly integrated wit PhasTramTM, IMS HEALTH Strategic Technologies' mobile solution for Microsoft Windows CE-based handheld PCs. . . managers can efficiently track and control sample inventories. . . territory or district sample records can be quickly reproduced for auditing. . . sample administrators receive advice and guidance on improving the efficiency and control of the sampling process); confirming the authority of the of the distributing representative to distribute the packet SampleTrakTM , a unique integrated product that provides pharmaceutical companies with a complete solution for meeting Prescription Drug marketing Act Final Rules in the U.S.); confirming the authority of the distributee to receive the packet (Validation is sent via IMS HEALTH Strategic Technologies' Pharmaceutical Relationship Management (PRM) solution directly to filed representatives equipped with laptop or handheld personal computers); transmitting an authorization code to the distributing representative (Field representatives are able to order samples and receive shipment acknowledgment via the Web and managers can efficiently track and control sample inventories. Additionally, SampleTrak is a unique, integrated product that provides pharmaceutical companies with a complete solution for meeting Prescription Drug Marketing Act Final Rules . . .); confirming the distribution request for propriety (sample administrators receive advice and guidance on improving the efficiency and control of the sampling process); and deleting a description of the packet's contents from the local inventory and the central inventory (managers can efficiently track and control sample

inventories); distributing the packet to the distributee (deliver the packet of articles to the distributee and get a signature acknowledging receipt of such packet).

Business Wire does not disclose evaluating the distribution request for meeting specific business logic specified by the pharmaceutical company but it would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the evaluation method of distribution as claimed because it would allow managers to efficiently track and control sample inventories for auditing and at the same time improve the efficiency and control of the sampling process) ;

As per claim 2, BusinessWire teaches that the controlled articles are prescription drug samples (see Title and SampleTrakTM . . . the drug sample management solution).

As per claim 3, BusinessWire teaches that the distributing representative is a pharmaceutical company's sale's representative and the distributees are licensed dispensing practitioners (Field representatives are able to order samples and receive shipment acknowledgment via the Web . . . SampleTrak enables pharmaceutical sample administrators to electronically validate a physician's eligibility to receive samples . . .).

As per claim 5, BusinessWire teaches that the request is received from the remote distributing representative over a communication path including a wireless link (SampleTrak can be seamlessly integrates with PhasTrakTM, IMS Health Strategic Technologies' mobile solution for Microsoft Windows CE-based handheld PCS.).

As per Claim 6, BusinessWire teaches the step of transmitting the request and authorization code to the central inventory's proprietor (Field Representatives are able to order samples and receive shipment acknowledgment via the Web, and managers can efficiently track

and control sample inventories (see claim 1). Additionally, SampleTrak is a unique, integrated product that provides pharmaceutical companies with a complete solution for meeting Prescription Drug Marketing Act Final Rules . . .)

As per claim 7, BusinessWire does not specifically teach transmitting a corrective action message to the distributing representative if the evaluation step results in an initial denial of authorization. Customer service is a key factor in the success of any business, whether it is brick and mortar or computerized. The ability to correct mistakes or errors in any system is a crucial factor in customer service. This practice is well known in the business community and would follow in a computerized process for the business community, particularly the pharmaceutical industry where competition is extremely fierce and the use of product samples can play an influential role on the success of a particular drug. Additionally, if a change in authorization is going to occur in the electronic system, the PDMA would require that there be an electronic record, as the sample would have to be requested and signed for under the appropriate rules.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have added the well-known step of transmitting a corrective action message to the distributing representative if the evaluation step results in an initial denial of the authorization of BusinessWire for the purpose of increasing customer utilization of the pharmaceutical product upon which the sample is based.

As per claim 8, BusinessWire teaches that the request is received from the remote distributing representative by means of electronic transmission of information entered on a sample disbursement form. SampleTrakTM is a unique integrated product that provides pharmaceutical companies with a complete solution for meeting Prescription Drug marketing

Act Final Rules ... SampleTrak can be seamlessly integrated with PhasTrak™, IMS HEALTH Strategic Technologies' mobile solution for Microsoft Windows CE-based handheld PCs. Field representatives are able to order samples . . . via the Web. . .).

As per claim 10, Business Wire teaches a specific business logic which provides pharmaceutical companies with a complete solution to meet requirements for distribution specified by government regulations as claimed.

Response to Arguments

4. Applicant's arguments filed on 05/05/2004 have been fully considered but they are not persuasive.

Applicant argues that the Business Wire system is not "a real time system" as claimed. Contrary to applicant's arguments, whenever the packet of articles is delivered to the distributee, a distributing representative armed with a statement containing the contents of articles for the receiving party (distributee) to sign acknowledging receipt of the articles. Whether or not the samples are to be distributed in the near future, the same process goes in order to account for some articles already distributed during inventory. In response to the hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based on hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill n the at the time the claimed invention was made and does not include knowledge gleaned only from applicant's disclosure, such a reconstruction is proper. See in re McLaughlin, 443 F.3d 1392, 170 USPQ 209, (CCPA 1971).

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5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ronald Laneau whose telephone number is (703) 305-3973. The examiner can normally be reached on Mon-Fri from 8:30am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Olszewski can be reached on (703) 308-5183. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ronald Laneau
Examiner
Art Unit 3627

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[Handwritten Signature] 8/3/04
Primary Examiner